UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,819	08/12/2002	Ronald Vale	UCSD-06783	1389

7590 12/22/2006

Medlen & Carroll
101 Howard Street Suite 350
San Francisco, CA 94105

EXAMINER	
SHIBUYA, MARK LANCE	
ART UNIT	PAPER NUMBER
1639	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/22/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/031,819	VALE ET AL.	
	Examiner	Art Unit	
	Mark L. Shibuya, Ph.D.,	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37 and 70-76* is/are pending in the application.

4a) Of the above claim(s) *76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37 and 70-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 37 and 70-76 are pending. Claim76 is withdrawn. Claims 37 and 70-75 are examined.

Election/Restrictions

2. Applicant's election of the species of CENP-E as a variety of ATPase, in the reply filed on 9/18/2006, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. The species of ATPase that is kinesin, as in claim 75, is rejoined.

4. Claim 76 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/18/2006.

Priority

5. This application is the national stage of PCT/US98/18368, filed 9/3/1998, (see WO 99/11814), which claims benefit of 60/057,895, filed 9/4/1997.

6. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Provisional Application No. 60/057,895, filed 9/4/1997, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Provisional Application No. 60/057,895, filed 9/4/1997, does not disclose detecting a change in coupling between ATP hydrolysis and force generation, wherein said change indicates that a compound modulates activity of a cytoskeletal system (as in clam 37). Therefore, priority is granted only to the international filing date of PCT/US98/18368, filed 9/3/1998.

7. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) and 120 as follows:

There is no common inventor between the instant application and Serial No.s 09/724,609, filed 11/28/200, now US 6,489,134; 09/226,772, filed 1/6/1999, now US

6,207,403; and 60/070,772, filed 1/8/1998. Applicant's correction of inventorship is insufficient, (see below, Correction of Inventorship).

Correction of Inventorship

8. The request to correct the inventorship of this nonprovisional application under 37 CFR 1.48(a) is deficient because:

> It lacks the written consent of any assignee of one of the originally named inventors.

See, MPEP 201.03 II. D.

The examiner respectfully notes that the written consent of every existing assignee of the original named inventors must be submitted. 37 CFR 1.48(a)(5). In the instant application, it would appear that this requirement pertains both to the Regents of the University of California and to Stanford University. The individuals signing on behalf of the assignees giving consent to the requested inventorship correction, should specifically state that he or she has the authority to act on behalf of the pertinent assignee. If this statement is already of record, the examiner would greatly appreciate being pointed to the papers that so state.

As the request is otherwise sufficient, the examiner expects that if the applicant perfects the correction of inventorship, the outstanding prior art rejections will be overcome for not having prior publication dates.

Specification

9. The amendment filed 6/19/2006, is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment to the first line of the specification states that the instant application is a and Serial No.s 09/724,609, filed 11/28/200, now US 6,489,134; 09/226,772, filed 1/6/1999, now US 6,207,403; and 60/070,772, filed 1/8/1998. Applicant's correction of inventorship is insufficient, (see below, Correction of Inventorship).

Applicant is required to cancel the new matter in the reply to this Office Action.

Withdrawn Claim Objection/Rejections

10. The following rejections are withdrawn in view of applicant's arguments and amendments to the claims.

11. Claims 37-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is for lack of written description.

12. Claims 37-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart et al., (June 1993) Proc. Natl. Acad. Sci. USA, Vol. 90, pp. 5209-5213 and Ashby et al., US 5,569,588 (10/96), (IDS entered 3/31/2003, reference no. 26).

New Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claim 73 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is for lack of written description.

This rejection is necessitated by applicant's amendments to the claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ 2d 1111, 1117, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the

'written description' inquiry, whatever is now claimed." The instant specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Claim 73 states: "The method of claim 37, wherein said compound which is identified is a lead therapeutic for animal or human disease." However, the specification does not disclose a single species of test compound that is identified as a lead therapeutic for animal or human disease. The specification does not present drawing or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the invention as in claim 73. Applicant does not describe methods for assaying for therapeutic potential in animals or humans. Thus the invention of claim 73 reaches through to a product that has not been adequately described. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, at 1483 (finding claims directed to *mammalian* FGF's were found to be unpatentable due to lack of written description for that broad class, where the specification provided only the *bovine* sequence).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

New Claim Rejections - 35 USC § 112, Second Paragraph

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 72 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "screened simultaneously" in claim 72 is a relative term which renders the claim indefinite. The term "simultaneously" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of closeness in time, and one of skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Maintained Claim Rejections - 35 USC § 102

16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

17. Claims 37 and 70-75 are rejected under 35 U.S.C. 102(e) as being anticipated by Goldstein et al., US 6,207,403 B1.

This rejection is maintained for the reasons of record as set forth in the previous Office action. The rejection is copied below for the convenience of the reader.

Applicant's amendments to the claims have necessitated grounds of rejection that are new.

The claims are drawn to methods of identifying a therapeutic lead compound that modulates activity of a cytoskeletal system, said method comprising: i) providing an assay mixture comprising a first component of a cytoskeletal system and a second component of a cytoskeletal system, wherein said first component and said second component specifically bind to each other; ii) contacting said assay mixture with a test compound to be screened for the ability to inhibit or enhance binding between said first component and said second component; iii) detecting a change in coupling between ATP hydrolysis and force generation; wherein said change indicates that said compound modulates activity of a cytoskeletal system.

Goldstein et al., US 6,207,403 B1, throughout the patent and the claims, discloses and claims methods of identifying a therapeutic lead compound (col. 2) that specifically modulates (e.g., inhibits) a kinesin "molecular motor" (col.s 3-4) binding activity to microtubules, which reads on inhibiting a cytoskeletal system, said method comprising: i) providing an assay mixture comprising a first kinesin motor, reading on a component of a cytoskeletal system, and microtubules, reading on a second microtubule component of a cytoskeletal system, (as in claims 38 and 39), wherein said first component and said second component specifically bind to each other; (see e.g., claim 1 of the '403 patent); ii) contacting said assay mixture with test compounds (at col. 4) derived from a marine sponge, Haliclona (also known as Adocia) sp., reading on test compounds to be screened for the ability to inhibit or enhance binding between said first component (kinesin motor) and said second component (microtubules); iii) assaying for inhibition at a kinesin ATPase site (col. 5), and inhibition at a microtubule binding site, (see claims 1 and 2 of the '403 patent), reading on detecting a change in coupling between ATP hydrolysis and force generation (col. 17, lines 18-49 and Table 2 (cf. Table 2 at p. 50 of the instant application)); wherein said change indicates that said compound modulates activity of a cytoskeletal system (see e.g., claim 1 of the '403 patent).

The amended claims are drawn to a method of identifying a therapeutic lead compound that modulates activity of a cytoskeletal system, said method comprising: i) providing an assay mixture comprising a first component of said cytoskeletal system and a second component of said cytoskeletal system, whereto said cytoskeletal system is a microtubule system, and wherein said first component comprises a kinesin motor protein and said second component comprises a tubulin protein that specifically bind to each other; ii) contacting said assay mixture with a test compound to be screened for the ability to inhibit or enhance binding between said first component and said second component; iii) detecting a change in coupling between ATP hydrolysis and force

generation; wherein said change indicates that said test compound modulates activity said cytoskeletal system.

Goldstein et al., at col. 25, lines 40-48, teach Drosophila kinesin ATPase protein purified from bacterial cells, reading on the assay mixture comprising a cell lysate, as in claim 71. Goldstein et al., at e.g., col. 26, lines 29-36, teach testing extracts from 268 marine sponges, which absent evidence to the contrary, would read on the simultaneous screening of at least 50 test compounds. Goldstein et al., at col. 27, Table 2, teach ATPases that include CENP-E, as in claim 74.

Response to Arguments

Applicant argues that the prior art reference of Goldstein et al., is not art, because the instant application is a continuation-in-part of the Goldstein reference.

Applicant's arguments, entered 6/19/2006, have been fully considered but they are not persuasive. The instant application is not a continuation-in-part of the patent of Goldstein et al., (see above, Priority), because the correction of inventorship is not sufficient (see, above Correction of Inventorship)

18. Claims 37 and 70-75 are rejected under 35 U.S.C. 102(a) as being anticipated by Sakowicz et al., (10 April 1998) Science Vol. 280, pp. 292-295.

This rejection is maintained for the reasons of record as set forth in the previous Office action. The rejection is copied below for the convenience of the reader.

Applicant's amendments to the claims have necessitated grounds of rejection that are new.

Sakowicz et al., (10 April 1998) Science Vol. 280, pp. 292-295, throughout the publication, discloses methods of identifying a therapeutic lead compound (p. 295) that specifically modulates (e.g., inhibits) a kinesin "molecular motor" (see, e.g., abstract) activity, which reads on inhibiting a cytoskeletal system, said method comprising: i) providing an assay mixture comprising a first kinesin motor, reading on a component of a cytoskeletal system, and microtubules, reading on a second microtubule component of a cytoskeletal system, (as in claims 38 and 39), wherein said first component and said second component specifically bind to each other; (p. 293, col. 1); ii) contacting said assay mixture with test compounds (p. 293, Figure 1) derived from a marine sponge, Haliclona (also known as Adocia) sp., reading on test compounds to be screened for the ability to inhibit or enhance binding between said first component (kinesin motor) and said second component (microtubules); iii) assaying for inhibition at a kinesin ATPase site (p. 293, Figure 2, and Table 1 (cf. Table 2 at p. 50 of the instant application)), and inhibition at a microtubule binding site, (pp. 293-94, bridging paragraph), reading on detecting a change in coupling between ATP hydrolysis and force generation (p. 293, col. 1); wherein said change indicates that said compound modulates activity of a cytoskeletal system (pp. 293-94, bridging paragraph).

Response to Arguments

Applicant argues that the prior art reference of Sakowicz et al., is not art, because the instant application claims benefit and priority that antedates the is a continuation-in-part of the reference of Sakowicz et al.

Applicant's arguments, entered 6/19/2006, have been fully considered but they are not persuasive. The instant application is not a continuation-in-part of the patent of Goldstein et al., (see above, Priority), because the correction of inventorship is not sufficient (see, above Correction of Inventorship). Therefore, the reference of Sakowicz et al., is antedated.

Conclusion

19. Claims 37 and 70-75 stand finally rejected. Claim 76 is withdrawn.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya, Ph.D., whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark L. Shibuya, Ph.D.,
Primary Examiner
Art Unit 1639